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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,706	07/20/2001	Paul F. Worley	JHUI1520-2	3044
28213	7590	11/14/2003	EXAMINER	
GRAY CARY WARE & FREIDENRICH LLP 4365 EXECUTIVE DRIVE SUITE 1100 SAN DIEGO, CA 92121-2133			ALLEN, MARIANNE P	
		ART UNIT	PAPER NUMBER	
		1631		

DATE MAILED: 11/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.	09/910,706	Applicant(s)	WORLEY ET AL.
Examiner	Marianne P. Allen	Art Unit	1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1) Responsive to communication(s) filed on 18 August 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

4) Claim(s) 1-43 is/are pending in the application.

4a) Of the above claim(s) 1-9, 12 and 24-43 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 10, 11 and 13-23 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) 1-43 are subject to restriction and/or election requirement.

### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) The translation of the foreign language provisional application has been received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.  
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)  
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_. 6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

Claims 24-43 and claim 12 (as presently amended) were withdrawn as being directed to an invention that is independent or distinct from the invention originally claimed

Applicant's traversal of their withdrawal is acknowledged. However, because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 10-11 and 13-23 are under consideration by the examiner.

Applicant's arguments filed 8/18/03 have been fully considered but they are not fully persuasive.

### ***Priority***

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. Presently, the relationship of the instant application to parent application 09/042,428 is not specified.

### ***Claim Rejections - 35 USC § 112***

Claims 10-11 and 13-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 10 has now been amended to reinsert the deleted limitations to “isolated” components. In response to applicant’s confusion, they are advised that the marked-up copy of claim 10 submitted 3/4/03 specifically deleted limitations to “isolated” components and the clean copy of the claims did not recite “isolated.” The present listing of the claim 10 now includes the “isolated” limitations again. However, applicant has now deleted limitations to “in the mammalian central nervous system.” The specification and originally filed claims are specifically directed to this concept and not a more general selection of compounds.

Claim 11 has been amended to refer to any metabotropic glutamate receptor (mGluR) rather than ones containing particular sequences and having particular activities. There is no basis for this more general concept. Applicant points to page 4, lines 3-7. However, lines 3-4 clearly contemplates only those metabotropic glutamate receptors comprising an SSSL or SSTL sequence and lines 4-6 clearly contemplates only those metabotropic glutamate receptors linked to phosphoinositidase C. Page 18 specifically is directed to identifying “compounds that interfere or modulate binding of the protein Homer to mGluR5 or mGluR1 $\alpha$ , and hence with PI-linked mGluR activity. The claims are not limited to any of these concepts. It is noted that metabotropic glutamate receptor (mGluR) is defined in the specification on page 7 as a glutamate binding site (note not necessarily a receptor per se) which is functionally linked (no definition as to what the metes and bounds of this phrase are) to either adenylate cyclase or phosphoinositidase c. (Note that the disclosure of mGluR with respect to assays is not as broad.) As evidenced by at least Figure 10, mGluR2 and mGluR4 do not bind Homer and using

these metabotropic glutamate receptors in the claimed method would not be operative. As such, it is not known what receptors beyond those specifically disclosed (mGluR5 or mGluR1 $\alpha$ ) are encompassed. It is not known what structural features such proteins would possess. Furthermore, with respect to claim 10 the specification discloses no binding proteins to which the synaptic activation protein having at least 70% sequence identity to a polypeptide having the sequence SEQ ID NO: 2 binds with the exception of mGluR5 or mGluR1 $\alpha$ . Applicant's arguments are with respect to enablement. This is not germane nor is it agreed with. The disclosure on page 17 that "Specific binding sites for additional synaptic activation proteins may have similar or divergent amino acid sequences that can be empirically determined, using methods similar to those discussed above" is not considered to be enabling but rather an invitation to experiment. It is not known what specific synaptic activation proteins nor what similar methods one of ordinary skill in the art is being directed to. The definition of "synaptic activation proteins" on page 2 is nebulous and not specific.

Again, claim 18 recites "glutathione-S-transferase (GST)-pulldown." There is no basis for this generic concept in the specification. Examples 6 and 7 do not disclose this terminology. Applicant argues that one of ordinary skill in the art would recognize that Examples 6 and 7 are pulldown assays. However, the claim is not directed to the specific assay in these examples and the specification does not contemplate this broad method.

Again, claims 18-19 are directed to detection limitations. However, these are not disclosed in Examples 6 and 7 with respect to methods of selecting a protein that interferes with binding of a synaptic activation protein. Examples 6 and 7 do not disclose adding a test compound and selecting a compound in view of changed binding when compared to a control.

Furthermore, Examples 6 and 7 are with respect to a particular Homer protein and mGluR binding protein and not the general concept set forth in claim 10. Applicant's arguments are unpersuasive. The specific example does not demonstrate contemplation of the broader concept claimed here.

Again, claims 16 and 20-23 are directed to assay limitations. However, these are disclosed on page 18 with respect to mGluR5 or mGluR1 $\alpha$  and PI-linked mGluR activity. They are not generally disclosed with respect to any binding protein to which the synaptic activation protein binds as in claim 10. The specific disclosure does not demonstrate contemplation of the broader concept claimed here.

Applicant is reminded that claims 13-23 were not originally filed claims.

A fair reading of the originally filed specification would not convey to one of ordinary skill in the art that what is presently claimed was the originally contemplated invention.

### *Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 703-308-0666. The examiner can normally be reached on Monday-Thursday, 5:30 am - 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703-308-4028. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

*Marianne P. Allen*  
Marianne P. Allen  
Primary Examiner  
Art Unit 1631

mpa